

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

| | | |
|------------------------------|---|----------------------------|
| BARDY DIAGNOSTICS, INC., |) | |
| |) | |
| Plaintiff/Counter-Defendant, |) | |
| |) | C.A. No. 24-1355-JDW |
| v. |) | |
| |) | JURY TRIAL DEMANDED |
| IRHYTHM TECHNOLOGIES, INC., |) | |
| |) | |
| Defendant/Counter-Plaintiff. |) | |

**PLAINTIFF BARDY DIAGNOSTICS, INC.’S ANSWER AND
COUNTERCLAIMS TO DEFENDANT IRHYTHM TECHNOLOGIES, INC.’S
THIRD AMENDED COUNTERCLAIMS**

Plaintiff Bardy Diagnostics, Inc. (“Bardy”) hereby answers Defendant iRhythm Technologies, Inc.’s (“iRhythm”) Third Amended Counterclaims as follows.

The headings in iRhythm’s Counterclaims are reproduced herein for the convenience of the reader. To the extent such headings include or infer allegations, they are denied.

NATURE OF THE ACTION

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising from Bardy’s infringement of U.S. Patent Nos. 12,133,734 (the “’734 patent”), 12,245,859 (the “’859 patent”), 12,245,860 (the “’860 patent”), 12,274,554 (the “’554 patent”), and 12,303,277 (the “’277 patent”) (collectively, the “iRhythm Asserted Patents”).

ANSWER: Bardy admits that the Counterclaims purport to state a cause of action for patent infringement of the ’734 patent, the ’859 patent, the ’860 patent, the ’554 patent, and the ’277 patent. Bardy denies that any such claim is meritorious.

2. iRhythm is the owner by assignment of the ’734 patent. A copy of the ’734 patent is attached as Exhibit 1. A copy of the ’734 patent is attached as Exhibit 1.

ANSWER: Bardy admits that Exhibit 1 contains a copy of U.S. Patent No. 12,133,734. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 2 and therefore denies them.

3. iRhythm is the owner by assignment of the '859 patent. A copy of the '859 patent is attached as Exhibit 11.

ANSWER: Bardy admits that Exhibit 11 contains a copy of U.S. Patent No. 12,245,859. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 3 and therefore denies them.

4. iRhythm is the owner by assignment of the '860 patent. A copy of the '860 patent is attached as Exhibit 12.

ANSWER: Bardy admits that Exhibit 12 contains a copy of U.S. Patent No. 12,245,860. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 4 and therefore denies them.

5. iRhythm is the owner by assignment of the '554 patent. A copy of the '554 patent is attached as Exhibit 15.

ANSWER: Bardy admits that Exhibit 15 contains a copy of U.S. Patent No. 12,274,554. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 5 and therefore denies them.

6. iRhythm is the owner by assignment of the '277 patent. A copy of the '277 patent is attached as Exhibit 18.

ANSWER: Bardy admits that Exhibit 18 contains a copy of U.S. Patent No. 12,303,277. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 6 and therefore denies them.

THE PARTIES

7. iRhythm is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 699 8th Street, Suite 600, San Francisco, CA 94103.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 7 and therefore denies them.

8. On information and belief, Bardy is a corporation organized and existing under the laws of the State of Delaware since 2013.

ANSWER: Admitted.

9. On information and belief, Bardy has its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

ANSWER: Admitted.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq., including specifically 35 U.S.C. § 271.

ANSWER: Bardy admits that the Counterclaim purports to state a claim under 35 U.S.C. § 1, et seq., including specifically 35 U.S.C. § 271. Bardy denies that any such claim is meritorious.

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Admitted.

12. On information and belief, as a corporation organized and existing under the laws of the state of Delaware, Bardy has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over Bardy. This Court also has personal jurisdiction over Bardy at least by virtue of Bardy filing the instant action in this Court.

ANSWER: The allegations contained in paragraph 12 contain legal conclusions to which no answer is required. To the extent a response is required, Bardy admits that it is a corporation organized and existing under the laws of the state of Delaware. Further, Bardy admits that this Court has personal jurisdiction over Bardy at least by virtue of Bardy filing the instant action in this Court. Bardy denies the remaining allegations contained in this paragraph.

13. On information and belief, Bardy is a commercial entity that makes, uses, advertises, offers for sale, and/or sells ECG monitors and ECG monitoring services. On information and belief, Bardy manufactures, makes, uses, advertises, offers for sale, and/or sells the Carnation Ambulatory Monitor (the “CAM patch”).

ANSWER: Bardy admits that it is a commercial entity that makes, uses, advertises, offers for sale, and/or sells the CAM patch. Bardy otherwise denies the allegations in this paragraph.

14. On information and belief, Bardy sells and offers to sell ECG monitors and ECG monitoring services, including the CAM patch, throughout the United States, including in this judicial district.

ANSWER: Bardy admits that it sells and offers to sell the CAM patch. Bardy otherwise denies the allegations in this paragraph.

15. On information and belief, Bardy makes the CAM patch available to healthcare providers and patients in Delaware.

ANSWER: Admitted.

16. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Bardy is incorporated in the State of Delaware and therefore resides in this judicial district.

ANSWER: Admitted.

BARDY AND BARDY'S CARNATION AMBULATORY MONITOR

17. On information and belief, Bardy is an ambulatory ECG monitoring solutions company founded in 2013, around 7 years after iRhythm was founded in 2006 and after iRhythm had already launched the Zio XT monitor. *See* <https://www.bardydx.com/>.

ANSWER: Bardy admits that it was founded in 2013 and that it provides ambulatory ECG monitoring solutions. Bardy lacks knowledge or information sufficient to form a belief as to the truth of the remainder of the allegations in paragraph 16 and therefore denies them.

18. On information and belief, Bardy received FDA approval for the CAM patch no earlier than Dec. 22, 2014. *See* https://www.accessdata.fda.gov/cdrh_docs/pdf14/K143067.pdf.

ANSWER: Bardy admits that it received FDA clearance for the CAM patch on December 22, 2014. Bardy otherwise denies the allegations in this paragraph.

19. On information and belief, Bardy publicly launched and began commercializing the 2-day CAM patch in the United States no earlier than 2015.

ANSWER: Denied.

20. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 2-day CAM patch in the United States.

ANSWER: Admitted.

21. On information and belief, Bardy publicly launched and began commercializing the 7-day CAM patch in the United States no earlier than 2015.

ANSWER: Denied.

22. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

ANSWER: Admitted.

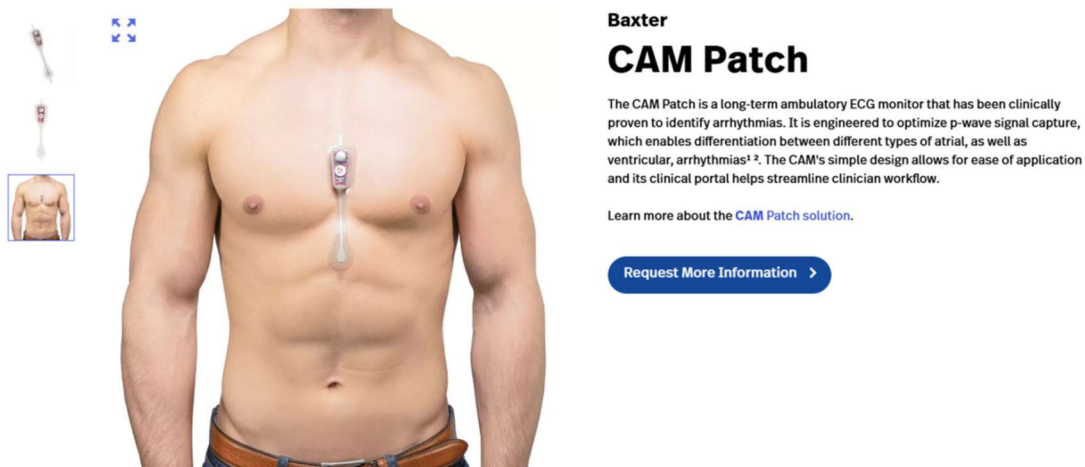
23. On information and belief, Bardy publicly launched and began commercializing the 14-day CAM patch in the United States on or around January 23, 2020. *See* Exhibit 2, Bardy Diagnostics, Inc., “Bardy Diagnostics Announces Commercial Launch of the 14-day Carnation Ambulatory Monitor (CAM) Patch,” PR Newswire (Jan. 23, 2020), <https://www.prnewswire.com/news-releases/bardy-diagnostics-announces-commercial-launch-of-the-14-day-carnation-ambulatory-monitor-cam-patch-300991978.html>.

ANSWER: Bardy admits that it publicly launched the 14-day CAM patch on or around January 23, 2020. Bardy otherwise denies the allegations in this paragraph.

24. On information and belief, Bardy continues to manufacture, use, sell, and offer to sell the 7-day CAM patch in the United States.

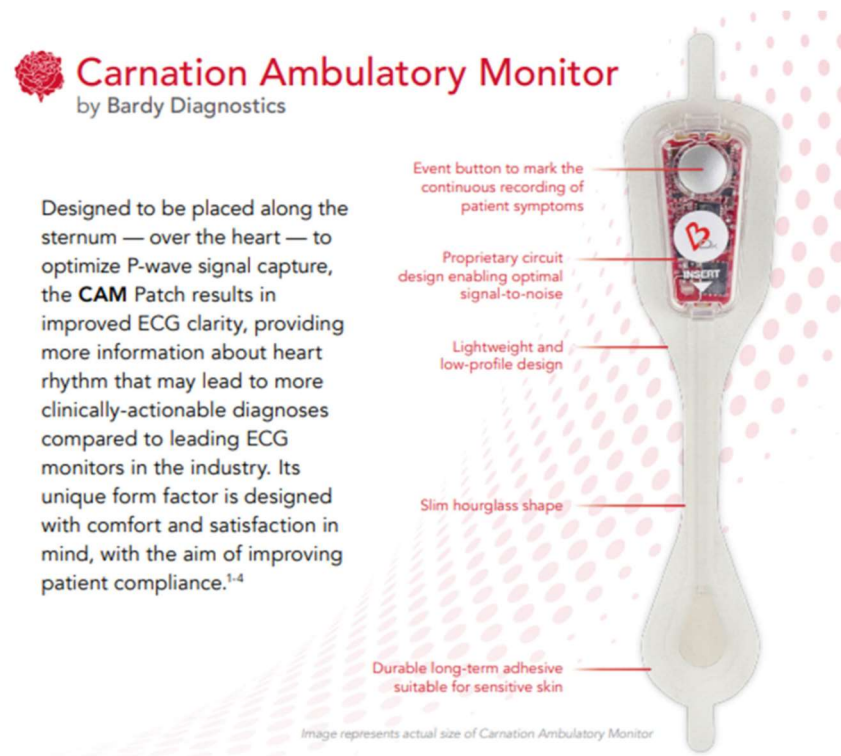
ANSWER: Admitted.

25. The CAM patch is an ambulatory ECG monitor that adheres to a user’s chest. *See, e.g.,* Exhibit 3, <https://www.hillrom.com/en/products/cam-patch/>.



ANSWER: Bardy admits that the CAM patch is an ambulatory ECG monitor that adheres to a user's chest. Bardy further admits that it describes the CAM patch on its website, accessible at <https://www.hillrom.com/en/products/cam-patch/>. Bardy otherwise denies the allegations in this paragraph.

26. As shown below, the CAM patch includes electrodes that capture p-wave signals, “which enables differentiation between different types of atrial, as well as ventricular, arrhythmias.” *Id.*; see also Exhibit 4, <https://www.bardydx.com/wp-content/uploads/2023/06/DWG000781B-CAM-Instructions-for-Use.pdf>. The CAM patch includes a purportedly “proprietary circuit” in a housing that is electronically connected to an electrode located on the patch. Exhibit 5, <https://www.bardydx.com/wpcontent/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf>.



ANSWER: Bardy admits that the website <https://www.hillrom.com/en/products/cam-patch/> states that “The CAM Patch is a long-term ambulatory ECG monitor that has been clinically proven to identify arrhythmias. It is engineered to optimize p-wave signal capture, which enables

differentiation between different types of atrial, as well as ventricular, arrhythmias.” Bardy further admits that the website <https://www.bardydx.com/wp-content/uploads/2022/12/DN000601A-14Day-Half-fold-CAM-Brochure.pdf> is a brochure for the Carnation Ambulatory Monitor™ that states, “Proprietary circuit design enabling optimal signal-to-noise.” Bardy otherwise denies the allegations in this paragraph.

27. On information and belief, and according to Bardy, the CAM patch provides a “[d]urable” adhesion that can last “[u]p to 2, 7, or 14 days.” See Exhibit 4.

Technical Specifications

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TECHNICAL SPECIFICATIONS

| ITEM | SPECIFICATION |
|-----------------------------|------------------------|
| Performance Characteristics | |
| ECG channels | 1 channel |
| Recording capacity | Up to 2, 7, or 14 days |
| Recording format | Continuous |
| Service life | Up to 2, 7, or 14 days |
| Shelf life | 24 months |

ANSWER: Bardy admits that its CAM patch can adhere to a patient for up to at least 14 days. Bardy otherwise denies the allegations in this paragraph.

28. On information and belief, and according to Bardy, the CAM patch “captures P-wave signals” from the heart using electrodes and transmits those to a purportedly “[p]roprietary circuit” located on the patch. Exhibit 5; see also Exhibit 6, https://www.bardydx.com/wp-content/uploads/2023/07/DN000697B-BDx_CAM_SpecSheet.pdf.

ANSWER: Bardy admits that Exhibit 5 purports to be a brochure for the CAM patch that states, “Designed to be placed along the sternum — over the heart — to optimize P-wave signal capture, the CAM Patch results in improved ECG clarity, providing more information about heart rhythm that may lead to more clinically-actionable diagnoses compared to leading ECG monitors in the industry.” Bardy further admits that Exhibit 5 states, “Proprietary circuit design enabling optimal signal-to-noise.” Bardy otherwise denies the allegations in this paragraph.

29. Given the facts alleged in this counterclaim, both stated above and set forth below and in Exhibit 7, 13, 14, 16, 17, and 19 Bardy's CAM patch directly infringes the claims of the iRhythm Asserted Patents, literally or under the doctrine of equivalents.

ANSWER: Denied.

FIRST COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,133,734

30. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 28 of Section I of iRhythm's Counterclaims and Answer.

ANSWER: Bardy incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 29 as its answers to paragraph 30.

31. The '734 patent duly and legally issued on November 5, 2024.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 and therefore denies them.

32. iRhythm owns all right, title, and interest in the '734 patent by assignment.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 31 and therefore denies them.

33. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 7, Bardy directly infringes at least claim 1 of the '734 patent, either literally or under the doctrine of equivalents.

ANSWER: Bardy admits that it makes, uses, sells and/or offers to sell the CAM patch in the United States. Bardy otherwise denies the allegations in this paragraph.

34. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '734 patent.

ANSWER: Denied.

35. On information and belief, Bardy has had knowledge of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '734 patent.

ANSWER: Bardy admits that iRhythm's counsel sent a letter to Bardy's counsel referencing the '734 patent on February 28, 2025. Bardy otherwise denies the allegations in this paragraph.

36. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 7 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

37. On information and belief, despite having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent since at least February 28, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

ANSWER: Denied.

38. Bardy has willfully infringed the '734 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the '734 patent and knowledge that the CAM patch infringes at least claim 1 of the '734 patent.

ANSWER: Denied.

39. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

ANSWER: Denied.

40. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '734 patent.

ANSWER: Denied.

41. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

ANSWER: Denied.

42. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

ANSWER: Denied.

SECOND COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,245,859

43. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 41 of Section I of iRhythm's Counterclaims and Answer.

ANSWER: Bardy incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 42 as its answer to paragraph 43.

44. The '859 patent duly and legally issued on March 11, 2025.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 44 and therefore denies them.

45. iRhythm owns all right, title, and interest in the '859 patent by assignment.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 45 and therefore denies them.

46. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 13, Bardy directly infringes at least claim 1 of the '859 patent, either literally or under the doctrine of equivalents.

ANSWER: Bardy admits that it makes, uses, sells and/or offers to sell the CAM patch in the United States. Bardy otherwise denies the allegations in this paragraph.

47. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '859 patent.

ANSWER: Denied.

48. On information and belief, Bardy has had knowledge of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '859 patent.

ANSWER: Bardy admits that iRhythm's counsel sent a letter to Bardy's counsel referencing the '859 patent on March 21, 2025. Bardy otherwise denies the allegations in this paragraph.

49. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 13 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

50. On information and belief, despite having knowledge of the '859 patent and knowledge that the CAM patch infringes at least claim 1 of the '859 patent since at least March 21, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

ANSWER: Denied.

51. Bardy has willfully infringed the '859 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the '859 patent and knowledge that the CAM patch infringes at least claim 1 of the '859 patent.

ANSWER: Denied.

52. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

ANSWER: Denied.

53. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '859 patent.

ANSWER: Denied.

54. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

ANSWER: Denied.

55. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

ANSWER: Denied.

THIRD COUNTERCLAIM: PATENT INFRINGEMENT OF
U.S. PATENT NO. 12,245,860

56. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 54 of Section I of iRhythm's Counterclaims and Answer.

ANSWER: Bardy incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 55 as its answers to paragraph 56.

57. The '860 patent duly and legally issued on March 11, 2025.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 57 and therefore denies them.

58. iRhythm owns all right, title, and interest in the '860 patent by assignment.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 58 and therefore denies them.

59. Bardy makes, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 14, Bardy directly infringes at least claim 1 of the '860 patent, either literally or under the doctrine of equivalents.

ANSWER: Bardy admits that it makes, uses, sells and/or offers to sell the CAM patch in the United States. Bardy otherwise denies the allegations in this paragraph.

60. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '860 patent.

ANSWER: Denied.

61. On information and belief, Bardy has had knowledge of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '860 patent.

ANSWER: Bardy admits that iRhythm's counsel sent a letter to Bardy's counsel referencing the '860 patent on March 21, 2025. Bardy otherwise denies the allegations in this paragraph.

62. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 14 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

63. On information and belief, despite having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent since at least March 21, 2025, Bardy has continued to make, use, sell, and offer to sell the CAM patch in the United States.

ANSWER: Denied.

64. Bardy has willfully infringed the '860 patent by continuing to make, use, offer to sell, and sell the CAM patch in the United States after having knowledge of the '860 patent and knowledge that the CAM patch infringes at least claim 1 of the '860 patent.

ANSWER: Denied.

65. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

ANSWER: Denied.

66. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '860 patent.

ANSWER: Denied.

67. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

ANSWER: Denied.

68. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

ANSWER: Denied.

FOURTH COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,274,554

69. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 67 of Section I of iRhythm's Counterclaims and Answer.

ANSWER: Bardy incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 68 as its answers to paragraph 69.

70. The '554 patent duly and legally issued on April 15, 2025.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 70 and therefore denies them.

71. iRhythm owns all right, title, and interest in the '554 patent by assignment.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 71 and therefore denies them.

72. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim charts attached as Exhibits 16 and 17, Bardy directly infringes at least claims 1 and 4 of the '554 patent, either literally or under the doctrine of equivalents.

ANSWER: Bardy admits that it makes, uses, sells and/or offers to sell the CAM patch in the United States. Bardy otherwise denies the allegations in this paragraph.

73. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '554 patent.

ANSWER: Denied.

74. On information and belief, Bardy has had knowledge of the issued claims of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the allowed claims of U.S. Patent Application No. 18/936,888, now issued as the claims of the '554 patent.

ANSWER: Bardy admits that iRhythm's counsel sent a letter to Bardy's counsel referencing U.S. Patent Application No. 18/936,888 on March 21, 2025. Bardy further admits that Exhibit C to the March 21, 2025, letter is titled "Allowed Claims of U.S. Patent Application 18/936,888." Bardy otherwise denies the allegations in this paragraph.

75. On information and belief, Bardy has also had knowledge of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '554 patent.

ANSWER: Denied.

76. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 16 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

77. On information and belief, Bardy has also had knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 17 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

78. On information and belief, despite having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least March 21, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

ANSWER: Denied.

79. On information and belief, despite having further knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent since at least April 22, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

ANSWER: Denied.

80. Bardy has willfully infringed the '554 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '554 patent and knowledge that the CAM patch infringes at least claims 1 and 4 of the '554 patent.

ANSWER: Denied.

81. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

ANSWER: Denied.

82. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '554 patent.

ANSWER: Denied.

83. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

ANSWER: Denied.

84. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

ANSWER: Denied.

FIFTH COUNTERCLAIM: PATENT INFRINGEMENT OF

U.S. PATENT NO. 12,303,277

85. iRhythm restates and incorporates by reference each of the averments of paragraphs 1 through 84 of Section I of iRhythm's Counterclaims and Answer.

ANSWER: Bardy incorporates by reference, as though fully set forth herein, its answers to paragraphs 1 through 84 as its answers to paragraph 85.

86. The '277 patent duly and legally issued on May 20, 2025.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 86 and therefore denies them.

87. iRhythm owns all right, title, and interest in the '277 patent by assignment.

ANSWER: Bardy lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 87 and therefore denies them.

88. Bardy makes, imports, uses, sells and/or offers to sell the CAM patch in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271 and, as set forth in the attached non-limiting claim chart attached as Exhibit 19, Bardy directly infringes at least claim 1 of the '277 patent, either literally or under the doctrine of equivalents.

ANSWER: Bardy admits that it makes, uses, sells and/or offers to sell the CAM patch in the United States. Bardy otherwise denies the allegations in this paragraph.

89. Bardy has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from iRhythm during the term of the '277 patent.

ANSWER: Denied.

90. On information and belief, Bardy has had knowledge of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent a letter to Bardy's counsel identifying the '277 patent.

ANSWER: Bardy admits that iRhythm's counsel sent a letter to Bardy's counsel referencing the '277 patent on May 20, 2025. Bardy otherwise denies the allegations in this paragraph.

91. On information and belief, Bardy has had knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, when iRhythm's counsel sent the claim chart attached as Exhibit 19 to this counterclaim to Bardy's counsel.

ANSWER: Denied.

92. On information and belief, despite having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent since at least May 20, 2025, Bardy has continued to make, use, sell, import, and/or offer to sell the CAM patch in the United States.

ANSWER: Denied.

93. Bardy has willfully infringed the '277 patent by continuing to make, use, offer to sell, import, and/or sell the CAM patch in the United States after having knowledge of the '277 patent and knowledge that the CAM patch infringes at least claim 1 of the '277 patent.

ANSWER: Denied.

94. As a result of the acts of infringement by Bardy, Bardy is liable to iRhythm in an amount that compensates iRhythm for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as determined by the Court under 35 U.S.C. § 284.

ANSWER: Denied.

95. This case is exceptional under 35 U.S.C. § 285, including due to Bardy's willful infringement of the '277 patent.

ANSWER: Denied.

96. Bardy's acts of infringement are likely to cause and, unless restrained or enjoined, will continue to cause irreparable injury and damage to iRhythm for which there is no adequate remedy at law.

ANSWER: Denied.

97. As a result of the acts of infringement by Bardy, iRhythm has suffered and/or will continue to suffer substantial damages in an amount to be proven at trial.

ANSWER: Denied.

RESPONSE TO RELIEF REQUESTED

As to all Relief Requested in the Counterclaims, Bardy denies that iRhythm is entitled to any relief as alleged or otherwise. All other allegations in the Counterclaims not specifically admitted or denied are hereby denied.

BARDY'S AFFIRMATIVE DEFENSES

Bardy incorporates by reference the claims detailed in its First Amended Complaint. Without conceding that any of the following necessarily must be pleaded as an affirmative defense, or that any of the following is not already at issue by virtue of the foregoing denials, and without prejudice to Bardy's right to plead and assert additional defenses as discovery into the facts of the matter warrant, Bardy asserts the following affirmative defenses:

FIRST DEFENSE: NON-INFRINGEMENT ('734 PATENT)

Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '734 patent. Bardy incorporates by reference the allegations of Count I of its Non-Infringement Counterclaim, below.

SECOND DEFENSE: NON-INFRINGEMENT ('859 PATENT)

Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '859 patent. Bardy incorporates by reference the allegations of Count II of its Non-Infringement Counterclaim, below.

THIRD DEFENSE: NON-INFRINGEMENT ('860 PATENT)

Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the

'860 patent. Bardy incorporates by reference the allegations of Count III of its Non-Infringement Counterclaim, below.

FOURTH DEFENSE: NON-INFRINGEMENT ('554 PATENT)

Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '554 patent. Bardy incorporates by reference the allegations of Count IV of its Non-Infringement Counterclaim, below.

FIFTH DEFENSE: INVALIDITY ('734 PATENT)

The claims of the '734 patent are each invalid for failure to comply with one or more of the requirements for patentability under United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112 and the rules, regulations, and laws pertaining thereto. Bardy incorporates by reference the allegations of Count V of its Invalidity Counterclaim, below.

SIXTH DEFENSE: INVALIDITY ('859 PATENT)

The claims of the '859 patent are each invalid for failure to comply with one or more of the requirements for patentability under United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112 and the rules, regulations, and laws pertaining thereto. Bardy incorporates by reference the allegations of Count VI of its Invalidity Counterclaim, below.

SEVENTH DEFENSE: INVALIDITY ('860 PATENT)

The claims of the '860 patent are each invalid for failure to comply with one or more of the requirements for patentability under United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112 and the rules, regulations, and laws pertaining thereto. Bardy incorporates by reference the allegations of Count VII of its Invalidity Counterclaim, below.

EIGHTH DEFENSE: INVALIDITY ('554 PATENT)

The claims of the '554 patent are each invalid for failure to comply with one or more of the requirements for patentability under United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112 and the rules, regulations, and laws pertaining thereto. Bardy incorporates by reference the allegations of Count VIII of its Invalidity Counterclaim, below.

NINTH DEFENSE: UNCLEAN HANDS AND/OR PATENT MISUSE

Faced with growing market competition from Bardy's 14-day CAM patch in the early 2020s, iRhythm filed the '734 patent's claims to the USPTO in June 2021. iRhythm added the tilt limitation in an attempt to cover Bardy's commercial product that was already on the market, despite the lack of written description and enablement support for this claim term. But the inventors never should have been awarded the '734 patent because the prosecuting attorney should not have filed amended claims with the tilt limitation, which he knew clearly lacked support under 35 U.S.C. § 112.

The '734 patent purportedly claims priority to U.S. Provisional Patent Application No. 61/334,081 (the "'081 application"). But the '081 application does not provide adequate support for the claims of the '734 patent, for example, due to the limitation in claim 1 reciting: "wherein the housing is configured to tilt at an angle relative to the lower adhesive layer in response to movement of the user" (referred to herein as the "tilt limitation"). The tilt limitation was added to the claims of the '734 patent in a preliminary amendment dated June 29, 2021, during prosecution of U.S. Patent Application No. 17/304,811 (the "'811 application"). '811 application, Preliminary Amendment dated June 29, 2021, at 2. When first introduced in the preliminary amendment, the applicant did not point to any written description support in the specification to support the newly added claims with the tilt limitation. The applicant simply, and erroneously, stated "No new matter has been added." *Id.* at 3.

Before adding the tilt limitation into the pending claims of the '811 application, iRhythm filed U.S. Patent Application No. 16/723,208 (the "'208 application"), which similarly claims priority to the same provisional patent application (the '081 application) as the '734 patent. The '208 application ultimately issued as U.S. Patent No. 11,141,091 (the "'091 patent"), which immediately precedes the '734 patent in the family of iRhythm patents related to the asserted '734 patent. After the first set of claims were rejected in the '208 application, David R. Schmidt requested and conducted an interview with the Examiner Cohen. One day later, David R. Schmidt filed an amended claim set adding substantially the same tilt limitation that he later added during the prosecution of the '811 application and that is now recited in the issued claims of the '734 patent. The applicant identified certain paragraphs and figures that allegedly provided Section 112 support for the tilt limitation. Examiner Cohen, however, rejected the amendment, finding the claims containing the tilt limitation lacked Section 112 support:

These claims set forth that the housing is configured to tilt; however, ***the term 'tilt' is never set forth in the disclosure.*** Applicant references paragraphs [0008] and [0077] of the PG Pub to support the limitation, ***but such support is not seen in those paragraphs or the identified drawing figures. Therefore, the meaning of the term with respect to the capability of the housing is unclear and lacks enablement.***

'208 application, Final Office Action dated December 11, 2020, at 3 (emphasis added).

After this rejection, the applicant cancelled the claims in the '208 application that improperly introduced the tilt limitation. A notice of allowance subsequently issued on May 18, 2021, and the '208 application then issued as the '091 patent.

One month later, iRhythm's same prosecuting attorney, David R. Schmidt, filed the '811 application, which was assigned to Examiner Antiskay, who was not the same examiner who previously rejected the tilt limitation in the '208 application as lacking Section 112 support. With this new application, the applicant again attempted to add the tilt limitation to the claims via a

preliminary amendment. Along with this preliminary amendment, the applicant did not provide any argument or cite to any disclosure in the specification to support the addition of the tilt limitation. Rather, the applicant misrepresented to the USPTO that “[n]o new matter has been added” despite Examiner Cohen’s previous confirmation that the tilt limitation was new matter and was inadequately supported in the specification common to both the ’208 application and the ’811 application.

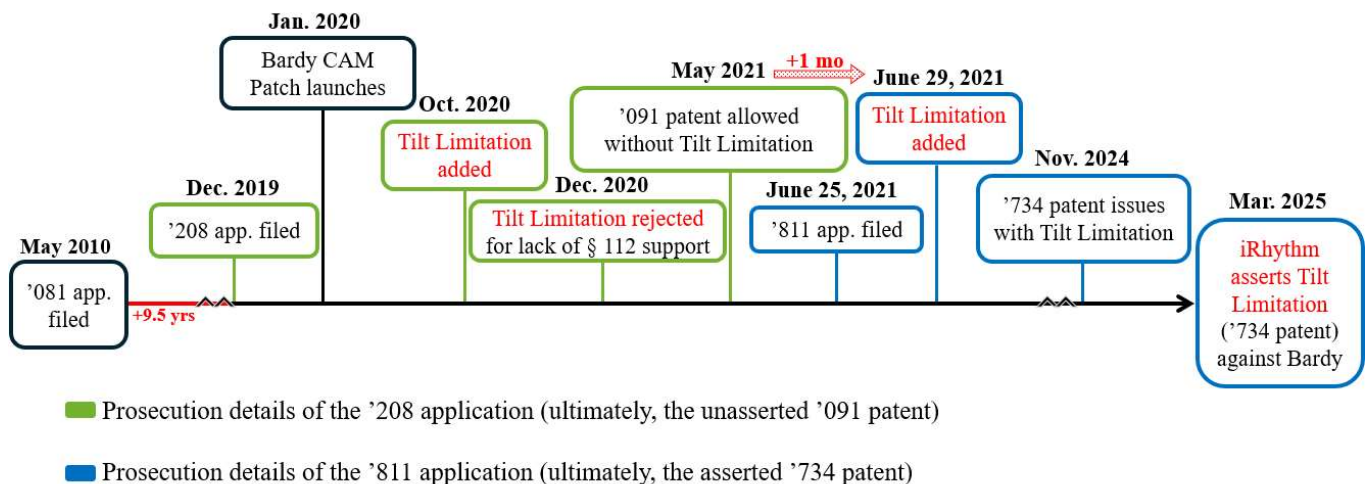
The applicant, and more specifically the prosecuting attorney, David R. Schmidt, was well-aware that the USPTO had already concluded that the tilt limitation was not supported by the specification. This critical fact may normally be known by the examiner who had previously rejected the limitation only months earlier in a related application. But here, the impropriety and impact of the amendment and the false representation that “[n]o new matter has been added” is underscored by the fact that Examiner Cohen had already found that the tilt limitation was new matter that was not supported, while Examiner Antiskay was assigned to handle the prosecution of the ’811 application.

The applicant and prosecuting attorney’s attempt to provide Examiner Cohen with specification support for the tilt limitation, juxtaposed with their failure to present any support or to inform Examiner Antiskay of the previous office action finding no Section 112 support for the tilt limitation only a few months after Examiner Cohen rejected the argument, further demonstrates iRhythm’s unclean hands.

Additionally, during prosecution of the ’811 application, in the first non-final Office action, Examiner Antiskay noted that “[t]he lengthy specification had not been checked to the extent necessary to determine the presence of all possible minor errors[,]” and requested “Applicant’s cooperation . . . in correcting any errors of which applicant may become aware in the

specification.” ’811 application, Non-Final Office Action dated January 23, 2024, at 2. Rather than cooperate, the applicant took advantage of Examiner Antiskay’s lack of familiarity with the ’811 application’s specification. Specifically, knowing that the tilt limitation was previously presented and found to lack Section 112 support in the specification (or any specification in the family), the ’734 patent issued on November 5, 2024, and iRhythm asserted the ’734 patent against Bardy on March 3, 2025. Now, iRhythm is knowingly attempting to enforce an invalid patent.

As further evidence of iRhythm’s misuse of the patent system and unclean hands, over the course of 14 years of prosecuting this patent family, iRhythm never obtained patent protection for the tilt limitation in any of the other six patents that purport to claim priority to the ’081 application. Set forth below is a timeline demonstrating when the tilt limitation was first introduced in the ’208 application and, its rejection, and iRhythm’s subsequent reintroduction of the tilt limitation in the ’811 application.



The same law firm, Knobbe, Martens, Olsen & Bear, LLP, and often the same attorney David R. Schmidt, prosecuted all of the applications in the '734 patent family for the entire 14 years, further supporting iRhythm’s knowledge of the alleged misconduct. Only after Bardy

commercially launched its 14-day CAM patch did iRhythm file these claims, knowing no support existed for the tilt limitation.

TENTH DEFENSE: PROSECUTION LACHES

iRhythm's claims are barred, in whole or in part, by prosecution laches. This doctrine may "render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution." *Symbol Techs., Inc. v. Lemelson Med, Educ. & Rsch. Found.*, 422 F.3d 1378, 1385 (Fed. Cir. 2005). While "[t]here are legitimate grounds for refiling a patent application which should not normally be grounds for a holding of laches," prosecution laches should apply in "egregious cases of misuse of the statutory patent system." *Id.* Such an egregious case is found here.

iRhythm filed the '081 application, to which the '734 patent purportedly claims priority, on May 12, 2010. The patent application from which the '734 patent issued was filed 11 years later on June 25, 2021. iRhythm filed U.S. Provisional Patent Application No. 61/756,326, to which the '859 and '860 patents purportedly claim priority, on January 23, 2013. The patent applications from which the '859 and '860 patents issued were filed 11.5 years later on July 29, 2024, and July 30, 2024, respectively.

Notably, for the first time in the application that led to the '734 patent, iRhythm filed and obtained claims directed to a "tilt" limitation, but the "tilt" limitation is not disclosed in the specification and was never claimed in any issued patent in the family in the 14 years of prosecuting this patent family.

With respect to the patent family that led to the issuance of the '859 and '860 patents and the patent family that led to the issuance of the '554 and '277 patents, iRhythm consistently sought claim coverage directed to an ECG monitor with two flexible wings and an electrode on each wing. Then, for the first time in the applications that led to the '859, '860, '554, and '277 patents, and

well after Bardy released its CAM Patch, iRhythm broadened the scope of its claims with respect to the electrode limitations in a plain attempt to cover Bardy's product that iRhythm now accuses of infringement.

Bardy was significantly prejudiced by iRhythm's delay at least because it made a substantial investment in and continued to independently develop the CAM patch, with no possibility of having notice of the expanded claim scope that now includes the tilt limitation ('734 patent), and the broadened electrode structure ('859, '860, '554, and '277 patents). These limitations were not disclosed in the specification of any earlier applications, making it impossible for Bardy to anticipate or avoid potential infringement. For at least the reasons set forth above, the iRhythm Asserted Patents are unenforceable under the doctrine of prosecution laches.

ELEVENTH DEFENSE: PROSECUTION HISTORY ESTOPPEL

iRhythm is estopped from asserting any interpretation of any claims of the iRhythm Asserted Patents that covers the accused CAM patch as such scope was surrendered during, and/or is inconsistent with any statements, representations, or admissions made during prosecution of the patent applications that resulted in the iRhythm Asserted Patents or any applications related thereto.

TWELFTH DEFENSE: GOOD FAITH

Bardy has engaged in all relevant activities in good faith, thereby precluding iRhythm, even if it prevails, from recovering its reasonably attorneys' fees or costs under 35 U.S.C. § 285.

THIRTEENTH DEFENSE: DEDICATION TO THE PUBLIC

The relief sought by iRhythm is barred, in whole or in part, because iRhythm dedicated to the public all methods, systems, and products disclosed in the iRhythm Asserted Patents but not literally claimed therein.

FOURTEENTH DEFENSE: LIMITATIONS ON DAMAGES AND COSTS

iRhythm's claim for damages is barred, in whole or in part, by at least 35 U.S.C. § 286. Further, iRhythm's claims for damages for alleged infringement of the iRhythm Asserted Patents are limited under 35 U.S.C. § 287 because iRhythm has failed to adequately mark its patented products. As a result, iRhythm is not entitled to damages for any alleged infringement that occurred before iRhythm gave actual notice of alleged infringement to Bardy. To the extent any claim of the iRhythm Asserted Patents are invalid, iRhythm is barred from recovering costs by 35 U.S.C. § 288.

FIFTEENTH DEFENSE: NO EXCEPTIONAL CASE FOR DEFENDANT

Bardy has not engaged in any conduct that would make this an exceptional case that would entitle iRhythm to an award of attorneys' fees or enhanced damages.

SIXTEENTH DEFENSE: NON-INFRINGEMENT ('277 PATENT)

Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '277 patent. Bardy incorporates by reference the allegations of Count IX of its Non-Infringement Counterclaim, below.

SEVENTEENTH DEFENSE: INVALIDITY ('277 PATENT)

The claims of the '277 patent are each invalid for failure to comply with one or more of the requirements for patentability under United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112 and the rules, regulations, and laws pertaining thereto. Bardy incorporates by reference the allegations of Count X of its Invalidity Counterclaim, below.

OTHER DEFENSES RESERVED

Bardy reserves the right to assert any additional defenses, at law or equity, that may be available now or in the future based on discovery or any factual investigation in this case.

BARDY'S COUNTERCLAIMS

Bardy Diagnostics, Inc. ("Bardy") hereby asserts the following counterclaims against iRhythm Technologies, Inc. ("iRhythm").

THE PARTIES

1. Bardy is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA.

2. As alleged by iRhythm in paragraph 7 of iRhythm's Third Amended Counterclaims and Answer (ECF No. 52), iRhythm is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 699 8th Street, Suite 600, San Francisco, CA 94103.

NATURE OF THE ACTION

3. Bardy brought this action against iRhythm for the infringement of the U.S. Patent No. 12,161,473 (the "'473 Patent"), U.S. Patent No. 12,171,562 (the "'562 Patent"), U.S. Patent No. 12,285,261 (the "'261 patent"), and U.S. Patent No. 12,310,735 (the "'735 Patent") (collectively, the "Bardy Asserted Patents").

4. iRhythm counterclaimed for a finding of infringement of the U.S. Patent Nos. 12,133,734 (the "'734 patent"), 12,245,859 (the "'859 patent"), 12,245,860 (the "'860 patent"), and 12,274,554 (the "'554 patent"), 12,303,277 (the "'277 patent") (collectively, the "iRhythm Asserted Patents") by Bardy.

JURISDICTION AND VENUE

5. The Court has subject matter jurisdiction over Bardy's Counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. The Court may properly exercise personal jurisdiction over iRhythm at least because iRhythm is deemed to reside in this judicial district by virtue of being incorporated in the

State of Delaware, and because iRhythm has asserted the iRhythm Asserted Patents against Bardy in the Counterclaims in this jurisdiction.

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and/or 1400, and because iRhythm has asserted the iRhythm Asserted Patents against Bardy in the Counterclaims in this jurisdiction.

**COUNT I: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 12,133,734**

8. Bardy incorporates by reference the allegations in Paragraphs 1-7 of these Counterclaims as though fully set forth herein.

9. In its Counterclaims, iRhythm alleges that Bardy has infringed and continues to infringe the '734 patent, either literally or under the doctrine of equivalents, and that Bardy will continue to engage in these acts.

10. Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '734 patent.

11. By way of example, and not by way of limitation, the '734 patent recites “wherein the housing is configured to tilt at an angle relative to the lower adhesive layer in response to movement of the user.” '734 patent, cl. 1. The CAM patch does not include a housing that is “configured to tilt at an angle relative to the lower adhesive layer in response to movement of the user,” as required by claim 1 of the '734 patent. Accordingly, the CAM patch does not infringe the sole independent claim of the '734 patent.

12. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '734 patent.

13. A judicial declaration that Bardy does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '734 patent is therefore necessary and appropriate to resolve this controversy.

14. iRhythm knew or should have known that Bardy has not and is not in any way infringing the '734 patent. This is therefore an exceptional case entitling Bardy to an award of its attorney fees pursuant to 35 U.S.C. § 285.

**COUNT II: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 12,245,859**

15. Bardy incorporates by reference the allegations in Paragraphs 1-14 of these Counterclaims as though fully set forth herein.

16. In its Counterclaims, iRhythm alleges that Bardy has infringed and continues to infringe the '859 patent, either literally or under the doctrine of equivalents, and that Bardy will continue to engage in these acts.

17. Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '859 patent.

18. By way of example, and not by way of limitation, the CAM patch does not have the claimed spring contacts as required by claim 1 of the '859 patent. Accordingly, the CAM patch does not infringe the sole independent claim of the '859 patent.

19. As evidenced by the allegations in the iRhythm Counterclaims, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '859 patent.

20. A judicial declaration that Bardy does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '859 patent is therefore necessary and appropriate to resolve this controversy.

21. iRhythm knew or should have known that Bardy has not and is not in any way infringing the '859 patent. This is therefore an exceptional case entitling Bardy to an award of its attorney fees pursuant to 35 U.S.C. § 285.

**COUNT III: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 12,245,860**

22. Bardy incorporates by reference the allegations in paragraphs 1-21 of these Counterclaims as though fully set forth herein.

23. In its Counterclaims, iRhythm alleges that Bardy has infringed and continues to infringe the '860 patent, either literally or under the doctrine of equivalents, and that Bardy will continue to engage in these acts.

24. Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '860 patent.

25. By way of example, and not by way of limitation, the CAM patch does not have the claimed spring contacts as required by claim 1 of the '860 patent. Accordingly, the CAM patch does not infringe the sole independent claim of the '860 patent.

26. As evidenced by the allegations in the iRhythm Counterclaims, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '860 patent.

27. A judicial declaration that Bardy does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '860 patent is therefore necessary and appropriate to resolve this controversy.

28. iRhythm knew or should have known that Bardy has not and is not in any way infringing the '860 patent. This is therefore an exceptional case entitling Bardy to an award of its attorney fees pursuant to 35 U.S.C. § 285.

**COUNT IV: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 12,274,554**

29. Bardy incorporates by reference the allegations in Paragraphs 1-28 of these Counterclaims as though fully set forth herein.

30. In its Counterclaims, iRhythm alleges that Bardy has infringed and continues to infringe the '554 patent, either literally or under the doctrine of equivalents, and that Bardy will continue to engage in these acts.

31. Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '554 patent.

32. By way of example, and not by way of limitation, the CAM patch does not include the claimed "electrical connection" as required by claim 1 of the '554 patent. Accordingly, the CAM patch does not infringe the sole independent claim of the '554 patent.

33. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '554 patent.

34. A judicial declaration that Bardy does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '554 patent is therefore necessary and appropriate to resolve this controversy.

35. iRhythm knew or should have known that Bardy has not and is not in any way infringing the '554 patent. This is therefore an exceptional case entitling Bardy to an award of its attorney fees pursuant to 35 U.S.C. § 285.

**COUNT V: DECLARATORY JUDGMENT OF
INVALIDITY OF U.S. PATENT NO. 12,133,734**

36. Bardy incorporates by reference the allegations in Paragraphs 1-35 of these Counterclaims as though fully set forth herein.

37. Bardy maintains that each and every claim of the '734 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112.

38. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '734 patent.

39. By way of example, and not by way of limitation, the claims of the '734 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 7,206,630 (Ex. A); U.S. Patent Publication No. 2008/0139953 (Ex. B); and/or U.S. Patent Publication No. 2002/0082491 (Ex. C).

40. A judicial declaration that the claims of the '734 patent are invalid is therefore necessary and appropriate to resolve this controversy.

**COUNT VI: DECLARATORY JUDGMENT OF
INVALIDITY OF U.S. PATENT NO. 12,245,859**

41. Bardy incorporates by reference the allegations in Paragraphs 1-40 of these Counterclaims as though fully set forth herein.

42. Bardy maintains that each and every claim of the '859 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112.

43. As evidenced by the allegations in the iRhythm Counterclaims, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '859 patent.

44. By way of example, and not by way of limitation, the claims of the '859 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 7,206,630 (Ex. A); U.S. Patent Publication No. 2008/0139953 (Ex. B); and/or U.S. Patent Publication No. 2002/0082491 (Ex. C).

45. A judicial declaration that the claims of the '859 patent are invalid is therefore necessary and appropriate to resolve this controversy.

**COUNT VII: DECLARATORY JUDGMENT OF
INVALIDITY OF U.S. PATENT NO. 12,245,860**

46. Bardy incorporates by reference the allegations in Paragraphs 1-45 of these Counterclaims as though fully set forth herein.

47. Bardy maintains that each and every claim of the '860 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112.

48. As evidenced by the allegations in the iRhythm Counterclaims, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '860 patent.

49. By way of example, and not by way of limitation, the claims of the '860 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 7,206,630 (Ex. A); U.S. Patent Publication No. 2008/0139953 (Ex. B); and/or U.S. Patent Publication No. 2002/0082491 (Ex. C).

50. A judicial declaration that the claims of the '860 patent are invalid is therefore necessary and appropriate to resolve this controversy.

**COUNT VIII: DECLARATORY JUDGMENT OF
INVALIDITY OF U.S. PATENT NO. 12,274,554**

51. Bardy incorporates by reference the allegations in Paragraphs 1-50 of these Counterclaims as though fully set forth herein.

52. Bardy maintains that each and every claim of the '554 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112.

53. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '554 patent.

54. By way of example, and not by way of limitation, the claims of the '554 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 7,206,630 (Ex. A); U.S. Patent Publication No. 2008/0139953 (Ex. B); and/or U.S. Patent Publication No. 2002/0082491 (Ex. C).

55. A judicial declaration that the claims of the '554 patent are invalid is therefore necessary and appropriate to resolve this controversy.

**COUNT IX: DECLARATORY JUDGMENT OF
NON-INFRINGEMENT OF U.S. PATENT NO. 12,303,277**

56. Bardy incorporates by reference the allegations in Paragraphs 1-55 of these Counterclaims as though fully set forth herein.

57. In its Counterclaims, iRhythm alleges that Bardy has infringed and continues to infringe the '277 patent, either literally or under the doctrine of equivalents, and that Bardy will continue to engage in these acts.

58. Bardy has not infringed, and currently does not infringe, under any theory of infringement, including either literally or under the doctrine of equivalents, any valid, enforceable claim of the '277 patent.

59. By way of example, and not by way of limitation, the CAM patch does not include the claimed “wherein the first substrate layer is positioned over the electrode and extends horizontally away from the housing beyond a boundary of the electrode; and wherein the second substrate layer is positioned over the first substrate layer and extends horizontally beyond a boundary of the first substrate layer” as required by claim 1 of the '277 patent. Accordingly, the CAM patch does not infringe the sole independent claim of the '277 patent.

60. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '277 patent.

61. A judicial declaration that Bardy does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '277 patent is therefore necessary and appropriate to resolve this controversy.

62. iRhythm knew or should have known that Bardy has not and is not in any way infringing the '277 patent. This is therefore an exceptional case entitling Bardy to an award of its attorney fees pursuant to 35 U.S.C. § 285.

**COUNT X: DECLARATORY JUDGMENT OF
INVALIDITY OF U.S. PATENT NO. 12,303,277**

63. Bardy incorporates by reference the allegations in Paragraphs 1-62 of these Counterclaims as though fully set forth herein.

64. Bardy maintains that each and every claim of the '277 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in United States Code, Title 35, including without limitation 35 U.S.C. §§ 101, 102, 103, 112.

65. As evidenced by the allegations in the iRhythm Counterclaim, there is now an actual, substantial, and continuing justiciable controversy between iRhythm and Bardy with respect to the alleged infringement of the '277 patent.

66. By way of example, and not by way of limitation, the claims of the '277 patent are invalid under 35 U.S.C. §§ 102 and/or 103 over U.S. Patent No. 7,206,630 (Ex. A); U.S. Patent Publication No. 2008/0139953 (Ex. B); and/or U.S. Patent Publication No. 2002/0082491 (Ex. C).

67. A judicial declaration that the claims of the '277 patent are invalid is therefore necessary and appropriate to resolve this controversy.

RELIEF REQUESTED

WHEREFORE, Bardy requests that the Court enter a judgment in its favor granting the following relief:

- A. Dismissing iRhythm's Counterclaims with prejudice;
- B. Denying all relief requested by iRhythm;
- C. Granting all relief requested by Bardy;
- D. Declaring that Bardy has not infringed the iRhythm Asserted Patents;
- E. Declaring that the iRhythm Asserted Patents are invalid;
- F. Declaring that this is an exceptional case, and awarding Bardy its reasonable attorneys' fees, costs, and expenses pursuant to 35 U.S.C. § 285; and
- G. Such other and further relief as this Court deems just and proper under the circumstances.

JURY DEMAND

Bardy demands trial by jury on all issues so triable.

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